

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
UOFMD.006AAPPLICATION NO.
09/839,894INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT
Altboum et al.FILING DATE
April 20, 2001GROUP
Unknown

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
2L	1	4,946,778	08/07/90	Ladner et al.			
2L	2	6,110,898	08/29/00	Malone et al.			
2L	3	6,187,344	02/13/01	Eljamal et al.			
2L	4	6,190,669	02/20/01	Noriega et al.			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

EXAMINER INITIAL		
2L	5	Altboum et al. (2001) Attenuated <i>Shigella flexneri</i> 2a ΔguaBA strain CVD 1204 expressing enterotoxigenic <i>Escherichia coli</i> (ETEC) CS2 and CS3 fimbriae as a live mucosal vaccine against shigella and ETEC infection. <i>Infection and Immunity</i> . 69(5):3150-3158.
2L	6	Black et al. (1981) Enterotoxigenic <i>Escherichia coli</i> diarrhoea: acquired immunity and transmission in an endemic area. <i>Bulletin of the World Health Organization</i> . 59(2):263-268.
2L	7	Black, R.E. (1986) Pathogens that cause travelers' diarrhea in Latin America and Africa. <i>Reviews of Infectious Diseases</i> . 8(2):S131-S135.
2L	8	Blomfield, et al. (1991) Allelic exchange in <i>Escherichia coli</i> using the bacillus subtilis sacB gene and a temperature-sensitive pSC101 replicon. <i>Molecular Microbiology</i> . 5(6):1447-1457.
2L	9	Bolivar, et al. (1977) Construction and characterization of new cloning vehicles. II. A multipurpose cloning system. <i>Gene</i> . 2:95-113.
2L	10	Chang et al. (1978) Phenotypic expression in <i>E. coli</i> of a DNA sequence coding for mouse dihydrofolate reductase. <i>Nature</i> . 275:617-624.
2L	11	Cote, et al. (1983) Generation of human monoclonal antibodies reactive with cellular antigens. <i>Proc.Natl.Acad.Sci.</i> 80:2026-2030.
2L	12	deHaan et al. (1991) The nucleotide sequence of a regulatory gene presnet on a plasmid in an enterotoxigenic <i>Escherichia coli</i> strain of serotype O167:H5. <i>FEMS Microbiology Letters</i> 83. 341-346.
2L	13	DuPont, et al. (1976) Comparative susceptibility of Latin American and united states students to enteric pathogens. <i>New England Journal of Medicine</i> . 1520-1521.
2L	14	Duthy et al. (1999) CS5 pilus biosynthesis genes from enterotoxigenic <i>Escherichia coli</i> O115:H40. <i>Journal of Bacteriology</i> . 181(18):5847-5851.
2L	15	deBoer et al. (1983) The tac promoter: A functional hybrid derived from the trp and lac promoters. <i>Proc.Natl.Acad.Sci.</i> 80:21-25.
2L	16	Engvall, E. (1980) Enzyme immunoasay ELISA and EMIT. <i>Meth. Enzymol.</i> 70:419-439.
2L	17	Felgner et al. (1987) Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure. <i>Proc.Natl.Acad.Sci.</i> 84:7413-7417.
2L	18	Fraley et al. (1981) New generation liposomes: the engineering of an efficient vehicle for intracellular delivery of nucleic acids. <i>TIBS</i> . 77-80.
2L	19	Froehlich et al. (1994) CooC and CooD are required for assembly of CS1 pili. <i>Molecular Microbiology</i> . 12(3):387-401.

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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
2L	20 Froehlich et al. (1995) Genes for CS2 pili of enterotoxigenic <i>Escherichia coli</i> and their interchangeability with those for CS1 pili. <i>Infection and Immunity</i> . 63(12):4849-4856.
2L	21 Gastra et al. (1996) Colonization factors of human enterotoxigenic <i>Escherichia coli</i> (ETEC) <i>Trends in Microbiology</i> . 4(11):444-452.
2L	22 Galen et al. (1999) Optimization of plasmid maintenance in the attenuated live vector vaccine strain salmonella typhi CVD 908-htrA. <i>Infection and Immunity</i> . 67(12):6424-6433.
2L	23 Goeddel et al. (1979) Direct expression in <i>Escherichia coli</i> of a DNA sequence coding for human growth hormone. <i>Nature</i> . 281:544-548.
2L	24 Goeddel et al. (1980) Synthesis of human fibroblast interferon by <i>E. coli</i> . <i>Nucleic Acids Research</i> . 8(18):4057-4075.
2L	25 Grewal et al. (1993) Induction of colonization factor antigen I (CFA/I) and coli surface antigen 4 (CS4) of enterotoxigenic <i>Escherichia coli</i> : relevance for vaccine production. <i>Vaccine</i> . 11(2):221-226.
2L	26 Hall et al. (1989) Purification and analysis of colonization factor antigen I, coli surface antigen 1, and coli surface antigen 3 fimbriae from enterotoxigenic <i>Escherichia coli</i> . <i>Journal of Bacteriology</i> . 171(11):6372-6374.
2L	27 Hamers et al. (1989) The nucleotide sequence of the first two genes of the CFA/I fimbrial operon of human enterotoxigenic <i>Escherichia coli</i> . <i>Microbial Pathogenesis</i> . 6:297-309.
2L	28 Hitzeman, et al. (1980) Isolation and characterization of the yeast 3-phosphoglycerokinase gene (PGK) by an immunological screening technique. <i>The Journal of Biological Chemistry</i> . 255(24):12073-12080.
2L	29 Holland et al. (1978) Isolation and identification of yeast messenger ribonucleic acids coding for enolase, glyceraldehyde-3-phosphat dehydrogenase, and phosphoglycerate kinase. <i>Biochemistry</i> . 17(23):4900-4907.
2L	30 Huse, et al. (1989) Generation of a large combinatorial library of the immunoglobulin repertoire in phage lambda. <i>Science</i> . 246:1275-1281.
2L	31 Hyams et al. (1991) Diarrheal disease during operating desert shield. <i>The New England Journal of Medicine</i> . 325(20):1423-1428.
2L	32 Jalajakumari, et al. (1989) Genes for biosynthesis and assembly of CS3 pili of CFA/II enterotoxigenic <i>Escherichia coli</i> : novel regulation of pilus production by bypassing an amber codon. <i>Molecular Microbiology</i> . 3(12):1685-1695.
2L	33 Jaye et al. (1983) Isolation of a human anti-haemophilic factor IX cDNA clone using a unique 52-base synthetic oligonucleotide probe deduced from the amino acid sequence of bovine factor IX. <i>Nucleic Acids Research</i> . 11(8):2325-2335.
2L	34 Jertborn et al. (1998) Safety and immunogenicity of an oral inactivated enterotoxigenic <i>Escherichia coli</i> vaccine. <i>Vaccine</i> . 16(2/3):255-260.
2L	35 Knutton et al. (1989) Adhesion and ultrastructural properties of human enterotoxigenic <i>Escherichia coli</i> producing colonization factor antigens III and IV. <i>Infection and Immunity</i> . 57(11):3364-3371.
2L	36 Kohler et al. (1975) Continuous cultures of fused cells secreting antibody of predefined specificity. <i>Nature</i> 256:495-497.
2L	37 Koprowski II et al. (2000) Attenuated <i>Shigella flexneri</i> 2a vaccine strain CVD 1204 expressing colonization factor antigen I and mutant heat-labile enterotoxin of enterotoxigenic <i>Escherichia coli</i> . <i>Infection and Immunity</i> . 68(9):4884-4892.
2L	38 Kotloff et al. (1995) Evaluation of the safety, immunogenicity, and efficacy in healthy adults of our doses of live oral hybrid <i>Escherichia coli-Shigella flexneri</i> 2a vaccine strain EcSf2a-2. <i>Vaccine</i> . 13(5):495-502.
2L	39 Levine et al. (1984) Coli surface antigens 1 and 3 of colonization factor antigen II-positive enterotoxigenic <i>Escherichia coli</i> : morphology, purification, and immune responses in humans. <i>Infection and Immunity</i> . 44(2):409-420.
2L	40 Levine, M.M. (1987) <i>Escherichia coli</i> that cause diarrhea: enterotoxigenic, enteropathogenic, enteroinvasive, enterohemorrhagic, and enteroadherent. <i>The Journal of Infectious Diseases</i> . 377-389.
2L	41 Levine, M.M. (2000) Immunization against bacterial diseases of the intestine. <i>Journal of Pediatric Gastroenterology and Nutrition</i> . 31:336-355.
2L	42 Manning, et al. (1985) Colonization factor antigen II (CFA/II) of enterotoxigenic <i>Escherichia coli</i> : molecular cloning of the CS3 determinant. <i>Mol. Gen. Genet.</i> 200:322-327.
2L	43 Mannino et al. (1988) Liposome mediated gene transfer. <i>BioTechniques</i> . 6(7):682-690.
2L	44 Maxam et al. (1980) Sequencing end-labeled DNA with base-specific chemical cleavages. <i>Methods in Enzymology</i> . 65:499-561.
2L	45 McConnell et al. (1980) Genetic control and properties of coli surface antigens of colonization factor antigen IV (PCF8775) of enterotoxigenic <i>Escherichia coli</i> . <i>Infection and Immunity</i> . 56(8):1974-1980.

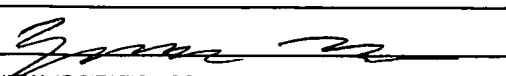
EXAMINER

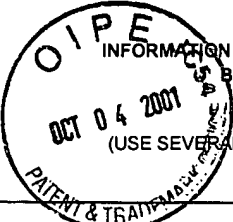
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		APPLICANT Altbaum et al.	
		FILING DATE April 20, 2001	GROUP Unknown

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)	
2L	46	McConnell et al. (1989) Antigenic homology within human enterotoxigenic <i>Escherichia coli</i> fimbrial colonization factor antigens: CFA/I, coli-surface-associated antigens (CS)1, CS2, CS4 and CS17. FEMS Microbiology Letters 61: 105-108.
2L	47	McConnell et al. (1991) Surveys of human enterotoxigenic <i>Escherichia coli</i> from three different geographical areas for possible colonization factors. Epidemiol.Infect. 106:477-484.
2L	48	Merson et al. (1976) Travelers' diarrhea in Mexico. A prospective study of physicians and family members attending a congress. The New England Journal of Medicine. 294(24):1299-1305.
2L	49	Messing et al. (1981) A system for shotgun DNA sequencing. Nucleic acids research. 9(2):309-321.
2L	50	Morrison et al. (1984) Chimeric human antibody molecules: mouse antigen-binding domains with human constant region domains. Proc.Natl.Acad.Sci. 81:6851-6855.
2L	51	Neuberger et al. (1984) Recombinant antibodies possessing novel effector functions. Nature. 312:604-608.
2L	52	Noriega et al. (1996) Further characterization of Δ aroA Δ virG <i>shigella flexneri</i> 2a strain CVD 1203 as a mucosal <i>Shigella</i> vaccine and as a live-vector vaccine for delivering antigens of enterotoxigenic <i>Escherichia coli</i> . Infection and Immunity. 64(1):23-27.
2L	53	Orlandi et al. (1989) Cloning immunoglobulin variable domains for expression by the polymerase chain reaction. Proc.Natl.Acad.Sci. 86:3833-3837.
2L	54	Qadri et al. (2000) Prevalence of toxin types and colonization factors in enterotoxigenic <i>Escherichia coli</i> isolated during a 2-year period from diarrheal patients in Bangladesh. Journal of Clinical Microbiology. 38(1):27-31.
2L	55	Rudin et al. (1994) Colonization factor antigens (CFAs) of enterotoxigenic <i>Escherichia coli</i> can prime and boost immune responses against heterologous CFAs. Microbial Pathogenesis. 16:131-139.
2L	56	Rudin et al. (1996) Monoclonal antibodies against fimbrial subunits of colonization factor antigen 1 (CFA/I) inhibit binding to human enterocytes and protect against enterotoxigenic <i>Escherichia coli</i> expressing heterologous colonization factors. Microbial Pathogenesis. 20:35-45.
2L	57	Rudin et al. (1997) Infection with colonization factor antigen I-expressing enterotoxigenic <i>Escherichia coli</i> boosts antibody responses against heterologous colonization factors in primed subjects. Epidemiol.Infect. 119:391-393.
2L	58	Sakellaris et al. (1998) New tools in an old trade: CS1 pilus morphogenesis. Molecular Microbiology. 30(4):681-687.
2L	59	Sakellaris et al. (1999) A conserved residue in the tip proteins of CS1 and CFA/I pili of enterotoxigenic <i>Escherichia coli</i> that is essential for adherence. PNAS. 96(22):12828-12832.
2L	60	Savalkoul et al. (1990) Expression of CFA/I fimbriae is positively regulated. Microbial Pathogenesis. 8:91-99.
2L	61	Siebenlist et al. (1980) E. coli RNA polymerase interacts homologously with two different promoters. Cell. 20:269-281.
2L	62	Sommerfelt et al. (1991) Presence of cfaD-homologous sequences and expression of coli surface antigen 4 on enterotoxigenic <i>Escherichia coli</i> ; relevance for diagnostic procedures. Microbial Pathogenesis. 11:297-304.
2L	63	Sommerfelt et al. (1992) Use of nonradioactive DNA hybridization for identification of enterotoxigenic <i>Escherichia coli</i> harboring genes for colonization factor antigen I, coli surface antigen 4, or putative colonization factor O166. Journal of Clinical Microbiology. 30(7):1823-1828.
2L	64	Sommerfelt et al. (1992) Genetic relationship of putative colonization factor O166 to colonization factor antigen I and coli surface antigen 4 of enterotoxigenic <i>Escherichia coli</i> . Infection and Immunity. 60(9):3799-3806.
2L	65	Svennerholm et al. (1988) Role of PCF8775 antigen and its coli surface subcomponents for colonization, disease, and protective immunogenicity of enterotoxigenic <i>Escherichia coli</i> in rabbits. Infection and Immunity. 56(2):523-528.
2L	66	Takeda et al. (1985) Construction of chimaeric processed immunoglobulin genes containing mouse variable and human constant region sequences. Nature. 314:452-454.
2L	67	Thomas et al. (1985) The possession of three novel coli surface antigens by enterotoxigenic <i>Escherichia coli</i> strains positive for the putative colonization factor PCF 8775. Journal of General Microbiology. 131:2319-2326.
2L	68	Vaitukaitis et al. (1971) A method for producing specific antisera with small doses of immunogen. J.Clin.Endocr. 33:988-991.
2L	69	Viboud et al. (1996) Binding of enterotoxigenic <i>Escherichia coli</i> expressing different colonization factors to tissue-cultured caco-2 cells and to isolated human enterocytes. Microbial Pathogenesis. 21:139-147.
2L	70	Wallace et al. (1981) The use of synthetic oligonucleotides as hybridization probes. Nucleic Acids Research. 9:879-895.
2L	71	Willshaw et al. (1988) Cloning of genes encoding coli-surface (CS) antigens in enterotoxigenic <i>Escherichia coli</i> . FEMS Microbiology Letters 49. 473-478.

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ZC	72	Willshaw et al. (1990) Structural and regulatory genes for coli surface associated antigen 4(CS4) are encoded by separate plasmids in enterotoxigenic <i>Escherichia coli</i> strains of serotype 025.H42. FEMS Microbiology Letters 68. 255-260.
ZC	73	Willshaw et al. (1991) Cloning of regulator genes controlling fimbrial production by enterotoxigenic <i>Escherichia coli</i> . FEMS Microbiology Letters 82. 125-130.
ZC	74	Winter, et al. (1991) Man-made antibodies. Nature. 349:293-299,
ZC	75	Wolf et al. (1989) Characterization of CS4 and CS6 antigenic components of PCF8775, a putative colonization factor complex from enterotoxigenic <i>Escherichia coli</i> E8775. Infection and Immunity. 57(1):164-173.
ZC	76	Wolf, et al. (1997) The CS6 colonization factor of human enterotoxigenic <i>Escherichia coli</i> contains two heterologous major subunits. FEMS Microbiology Letters. 148:35-42.

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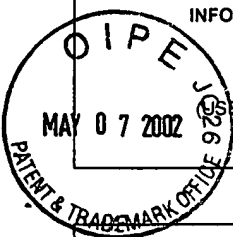
EXAMINER <i>Garrett 2m</i>	DATE CONSIDERED <i>7-18-2002</i>
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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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							YES	NO
2L	1	WO 96 38171	12/5/96					

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)		
2L	2	Altboum Z et al., <i>Construction of a Bivalent Shigella-ETEC Vaccine Expressing CS2 and CS3 Pili</i> , ABSTRACT OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR, Vol. 99, 1999, page 293, 99 th General Meeting of the American Society for Microbiology; Chicago, IL	
2L	3	Altboum Z et al., <i>Construction of a Bivalent Shigella-ETEC Vaccine Expressing CS4 Pili</i> , ABSTRACT OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR, Vol. 100, 2000, page 303, 100 th General Meeting of the American Society for Microbiology; Los Angeles, CA	
2L	4	Koprowski H II et al., <i>Construction and Analysis of a Shigella Flexneri 2a/CFA/I Vaccine</i> , Abstracts of the General Meeting of the American Society For, Vol. 99, 1999, p. 293, 99 th General Meeting of the American Society for Microbiology; Chicago, IL.	
2L	5	Pilsel Holger et al., <i>Characterization of Colicin S4 and its Receptor, OmpW, a minor protein of the Escherichia Coli outer membrane.</i> , Journal of Bacteriology, Vol. 181, No. 11, June 1999, pp. 3578-3581.	
2L	6	DATABASE EBI "online", Hinxton, UK; May 7, 1996, Van Dijk	

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